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(54) **Intraluminal stent**

Instraluminarer Stent

Stent instraluminaire

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Description

The present invention generally relates to a vascular pr sthesis, and more particularly t an intraluminal stent which has a flexible and elastic tubular construction with sufficient hoop strength to prevent elastic recoil of balloon-resistant strictures or to produce delayed dilation of those strictures.

WO 92/00043 describes a body implantable stent consisting of stent segments being of open weave construction, formed of multiple braided, helically wound strands of resilient material. The stent is elastically deformed to a reduced radius when deployed. When released after positioning, the stent self-expands radially. Due to the woven structure of the segments, the ability to be radially reduced and expanded depends on the movability of the strands within the woven structure.

Palmaz U.S. Patent No. 4,733,665 discloses a balloon-expandable intraluminal graft, including an embodiment comprising a wire mesh tube. Intersecting wire members, secured to one another at their intersections by welding, soldering or gluing, form the wire mesh and define a diamond-like pattern. This structure provides a relatively high resistance to radial collapse; but it suffers a number of disadvantages. First it is a rigid structure which cannot easily assume the configuration of a curved vessel which receives it. Second one must use a balloon catheter to expand and implant it. This requirement limits the length of the graft, as does the rigidity.

Other prior stents have more flexible constructions; but they suffer other disadvantages. Wiktor U.S. Patent No. 4,886,062, for example, discloses a stent which has a relatively flexible construction. This construction includes a deformable wire bent into a zig-zag design and coiled in a spiral fashion. The resulting wire tube has an open configuration with a reduced hoop strength. Each hoop lies essentially isolated from the adjacent hoops and does not obtain substantial support from them. Moreover, the open configuration increases the risk that plaque elements may herniate through the coil. Finally, one must use a balloon catheter to expand and implant it. Thus, the length of the stent cannot exceed the balloon length of available balloon catheters.

The intraluminal stent of the present invention avoids the disadvantages of the prior art stents and grafts. It has sufficient hoop strength to prevent elastic recoil of balloon-resistant strictures. The stent of the present invention has a flexible construction which allows it to follow the curvature of the vessel which receives it. It has an elastic construction which allows implantation without a balloon catheter. This elasticity further allows compression of the structure and recoil upon implantation to produce delayed dilation of the receiving vessel.

SUMMARY OF THE INVENTION

In accordance with an embodiment of the present invention, an intraluminal stent includes a predetermined length of wire having a sinuous or zig-zag configuration and defining a continuous helix with a plurality of connected spirals or hoops. A plurality of loop members connect adjacent apices of adjacent helix hoops. The stent is compressible and self-expandable substantially to the configuration prior to compression.

In accordance with a preferred embodiment of the present invention, an intraluminal stent includes the continuous helix and the plurality of loop members described above. It also includes a prosthetic graft disposed longitudinally of the wire helix within its central opening (or around the wire helix). One or more of the loop members secures the graft to the wire helix. This graft is a flexible, tubular shell which allows the wire helix to contract and recoil.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of this invention one should now refer to the embodiments illustrated in greater detail in the accompanying drawings and described below by way of examples of the invention. In the drawings:

FIG. 1 is a perspective view of the intraluminal stent of the present invention;

FIGS. 2-4 are side elevation views of a suture connection for the stent of FIG. 1;

FIG. 5 is a sectional view of the devices used to implant the stent of FIG. 1;

FIG. 6 is a sectional view of the sheath and catheter devices used to implant the stent, showing the catheter holding the stent in place as the sheath moves out of the body vessel.

FIG. 7 is a side elevation view of a preferred embodiment of the stent of the present invention;

FIG. 8 is a sectional view taken along the line 8-8 in FIG. 7;

FIG. 9 is a partial perspective view of the stent of FIG. 7, showing a suture connection for the stent; and

FIG. 10 is a perspective view of the mandrel used to form the wire helix of the present invention.

While the applicant will describe the invention in connection with preferred and alternative embodiments, one should understand that the invention is not limited to those embodiments. Furthermore, one should understand that the drawings are not necessarily to scale. In certain instances, the applicant may have omitted details which are not necessary for an understanding of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Turning now to the drawings, FIG. 1 shows the intraluminal stent of the present invention generally at 10. This stent includes a wire body 11 made out of a predetermined length of wire having a sinuous or zig-

zag configuration and defining a continuous helix with a series of connected spirals or hoops. It also includes loop members 12 which connect adjacent apices of adjacent helix hoops to help define the tubular stent. The loop members 12 may connect all or some of the pairs of adjacent apices.

The wire body 11 is an elastic alloy which provides radial elasticity for the stent. Preferably, it is a nitinol alloy which has superior elasticity and fatigue resistance. The wire has a round cross-section; but its cross-section may also be any one of a variety of shapes, e.g., triangular, rectangular, etc. Alternatively, any material of sufficient strength and elasticity and the other properties identified above may form the wire body, including stainless steel, tantalum, titanium, or any one of a variety of plastics.

The loop members 12 connect adjacent apices of adjacent hoops of the wire body 11 so that the adjacent apices abut each other (See FIGS. 2-4). Thus, each hoop receives support from adjacent hoops, increasing the hoop strength of the overall stent structure and minimizing the risk of plaque herniation. The loop members 12 are ligatures of suture material with the ends tied together to form a loop. This material is polypropylene material or any other biocompatible material of sufficient strength. Although sutures are the preferred connecting means, other connecting means such as staples and rings made of metal or plastic may provide the same function.

The stent structure of the present invention allows compression prior to implantation in a human or animal vessel. After implantation, upon release of the compressive force, the stent structure recoils (or self-expands) to its original configuration. Thus, it continues to provide dilating force in the implanted state. The structure provides flexibility which allows the stent to follow the curvature of the vessel which receives it.

Turning now to FIGS. 7-9, a preferred embodiment of the present invention includes the wire body and suture connections described above. This embodiment also includes a prosthetic graft 13 disposed inside the central opening of the wire body. The graft 13 is a round, open tube made of polytetrafluoroethylene (PTFE), dacron (Registered Trade Mark of a polyethylene terephtalate fiber) or any other suitable biocompatible material. It has an outside diameter slightly smaller than the inside diameter of the wire body 11. One or more hoop members connect the graft 13 to the wire body 11 as shown in FIG. 9. In place, the graft closes the diamond shaped openings of the stent structure to further minimize plaque herniation and minimize the flow of fluid and cellular elements through the structure.

Alternatively, the graft 13 may lie around the outside of the wire helix. Furthermore, the graft 13 may be coextensive with the wire helix; or it may be shorter than the wire helix. Finally, the graft 13 may include a plurality of segments disposed within the wire helix or around the outside of the helix.

The method of making the stent of the present invention includes bending a predetermined length of elastic wire in a zig-zag fashion between the pins 14 of the mandrel 15 and around the mandrel, thus forming a helix (See FIG. 10). The next step includes removing the helix from the mandrel by removing the pins and sliding the helix off the mandrel. The process further includes connecting adjacent apices of adjacent helix hoops. A fabricator makes each connection by placing a ligature of suture material (or any other suitable material) around the wire segments which define two adjacent apices and tying the ends of the ligature together to form a loop. In applications in which the wire body is nitinol wire, the process includes securing the ends of the wire to the mandrel and annealing the wire to a predetermined temperature (and thus imparting a thermal memory for the annealed shape) before removing the helix from the mandrel.

The method of implanting the stent of the present invention includes compressing it and placing it into the central bore of an introducing device 16. The next step includes coupling the device 16 with the hub 17 of a sheath 18 which extends to the implantation location. The next step involves using a catheter 19 to push the compressed stent to the predetermined location and to hold the stent at the location with the catheter, and then removing the sheath. The final step involves removal of the catheter to allow the stent to recoil.

In applications in which the wire body is a nitinol metal, a user reduces the diameter of the stent by first cooling it, e.g., by submerging it in ice water. This cooling places the nitinol in a martensitic phase and facilitates manual reduction of the diameter and insertion of the stent in the central bore of the device 16. The device 16 and the sheath 18 restrain the stent until deployment in a predetermined location. At that location in a subject's body, body fluids warm the nitinol and place it in an austenitic phase which is the stable phase of this metal and which corresponds to a fully opened or expanded configuration of the stent (to its original annealed diameter).

While the above description and the drawings illustrate one embodiment and an alternative, one should understand, of course, that the invention is not limited to those embodiments. Those skilled in the art to which the invention pertains may make other modifications and other embodiments employing the principals of this invention, particularly upon considering the foregoing teachings. For example, one may use a deformable material to construct the wire body 11 of the stent and then use a balloon catheter to deploy it. The applicant, therefore, by the appended claims, intends to cover any modifications and other embodiments which incorporate those features which constitute the essential features of this invention.

Claims

1. An intraluminal stent (10) comprising: a predetermined l ngth of elastic wire (11) having a sinuous

or zig-zag configuration and defining a continuous helix with a plurality of hoops; a plurality of loop members (12) for connecting adjacent apices of adjacent helix hoops; the stent (10) being compressible and self-expandable substantially to a pre-compressed configuration.

2. The stent of claim 1, wherein the loop members (12) connect the adjacent apices of the helix hoops in abutting relation.

3. The stent of claim 1 or 2, wherein the elastic wire is a high temperature shape memory nitinol alloy.

4. The stent according to one of the claims 1 to 3, wherein the loop members (12) have a substantially greater flexibility than the wire.

5. The stent according to claim 4, wherein each loop member (12) includes a single ligature of suture material tied into a loop.

6. The stent of claim 5, wherein the suture material is made of polypropylene.

7. The stent according to one of the claims 1 to 6, further comprising a tubular graft member (13) secured to the wire helix with at least one of the loop members (12).

8. The stent of claim 7, wherein the graft member (13) lies within the wire helix.

9. The stent of claim 6, wherein the plurality of the loop members (12) extend around adjacent apices of wire, into a graft member (13) through openings in the graft member (13) and out of the graft member (13) through other openings.

10. The stent according to one of the claims 7 to 9, wherein the graft member (13) is a tube of polytetrafluoroethylene.

11. The stent according to one of the claims 7 to 9, wherein the graft member (13) is made of a polyethylene terephtalate fiber.

12. A method of forming a compressible and self-expandable tubular intraluminal stent (10) comprising: bending a predetermined length of elastic wire (10) into a sinuous or zig-zag configuration and simultaneously into a helix of predetermined diameter and length; connecting together a plurality of adjacent apices of adjacent helix hoops by means of loop members (12), to define the stent.

Patentansprüche

1. Intraluminale Streckvorrichtung (10) mit einem elastischen Draht (11) vorbestimmter Länge mit einer Sinus- oder Zickzack-Konfiguration, der eine kontinuierliche Helix mit einer Mehrzahl Ringen definiert; einer Mehrzahl von Schlaufenelementen (12) zum Verbinden benachbarter Spitzen von benachbarten Helixringen; wobei die Streckvorrichtung (11) kompresibel und selbstexpandierend ist, im wesentlichen zu einer vorkomprimierten Konfiguration.

2. Streckvorrichtung nach Anspruch 1, worin die Schlaufenelemente (12) die benachbarten Spitzen der Helixringe in aneinander stoßendem Verhältnis verbindet.

3. Streckvorrichtung nach Anspruch 1 oder 2, worin der elastische Draht eine Hochtemperaturformspeicher-Nitinollegierung ist.

4. Streckvorrichtung gemäß einem der Ansprüche 1 bis 3, worin die Schlaufenelemente (12) im wesentlichen eine größere Flexibilität haben als der Draht.

5. Streckvorrichtung gemäß Anspruch 4, worin jedes Schlaufenelement (12) eine einfache Ligatur aus zu einer Schlaufe geschnürtem Nahtmaterial enthält.

6. Streckvorrichtung nach Anspruch 5, worin das Nahtmaterial aus Polypropylen gemacht ist.

7. Streckvorrichtung gemäß einem der Ansprüche 1 bis 6, das weiterhin ein rohrförmiges Pfropfenelement (13) aufweist, das mit mindestens einem der Schlaufenelemente (12) an der Drahthelix befestigt ist.

8. Steckvorrichtung nach Anspruch 7, worin das Pfropfenelement (13) innerhalb der Drahthilex liegt.

9. Steckvorrichtung nach Anspruch 6, worin sich die Mehrzahl der Schlaufenelemente (12) um benachbarte Spitzen des Drahtes erstreckt, in einem Pfropfenelement (13) durch Öffnungen des Pfropfenelementes (13) und aus dem Pfropfenelement (13) durch andere Öffnungen heraus.

10. Streckvorrichtung gemäß einem der Ansprüche 7 bis 9, worin das Pfropfenelement (13) ein Rohr aus Polythetraetyhlen ist.

11. Streckvorrichtung nach einem der Ansprüche 7 bis 9, worin das Pfropfenelement (13) aus einer Polyethylenterephthalate-Faser besteht.

12. Verfahren zum Formen einer kompressiblen und selbst expandierenden rohrartigen intraluminalen Streckvorrichtung (10) mit: Biegen eines elastischen Drahtes (10) vorbestimmter Länge in eine Sinus- oder Zickzackkonfiguration und gleichzeitig

in eine Helix vorbestimmten Durchmessers und Länge; miteinander Verbinden einer Mehrzahl benachbarter Spitzen von benachbarten Helixringen mit Hilfe von Schlaufenelementen (12), zum Definieren der Streckvorrichtung.

Revendications

1. Stent intraluminaire (10) comprenant : une longueur déterminée de fil élastique (11) ayant une configuration sinueuse ou en zigzag et formant une hélice continue ayant une série de spires, et une série d'éléments boucles (12) joignant les sommets voisins des spires d'hélice voisines, ce stent (10) étant compressible et auto-expansible sensiblement jusqu'à une configuration précomprimée.

2. Stent selon la revendication 1, dans lequel les éléments boucles (12) joignent les sommets voisins des spires d'hélice en position bout à bout.

3. Stent selon l'une des revendications 1 et 2, dans lequel le fil élastique est en alliage nitinol à mémoire de forme à haute température.

4. Stent selon l'une des revendications 1 à 3, dans lequel les éléments boucles (12) sont sensiblement plus souples que le fil.

5. Stent selon la revendication 4, dans lequel chaque élément boucle (12) comporte une simple ligature de matériau de suture attachée en une boucle.

6. Stent selon la revendication 5, dans lequel le matériau de suture est en polypropylène.

7. Stent selon l'une des revendications 1 à 6, comprenant en outre un élément greffe tubulaire (13) fixé à l'hélice de fil par au moins un des éléments boucles (12)..

8. Stent selon la revendication 7, dans lequel l'élément greffe (13) est situé à l'intérieur de l'hélice de fil.

9. Stent selon la revendication 6, dans lequel les éléments boucles (12) s'étendent autour de sommets voisins de fil, entrent dans un élément greffe (13) par des ouvertures faites dans celui-ci et sortent de celui-ci par d'autres ouvertures.

10. Stent selon l'une des revendications 7 à 9, dans lequel l'élément greffe (13) est un tube de polytétrafluoréthylène.

11. Stent selon l'une des revendications 7 à 9, dans lequel l'élément greffe (13) est fait d'une fibre de polyéthylène téréphtalate.

12. Procédé de formation d'un stent intraluminaire tubulaire compressible et auto-expansible (10), comprenant : le pliage d'une longueur déterminée de fil élastique (11) en une configuration sinueuse ou en zigzag et en même temps en une hélice de diamètre et de longueur déterminés, et la jonction d'une série de sommets voisins de spires d'hélice voisines au moyen d'éléments boucles (12), pour former le stent.

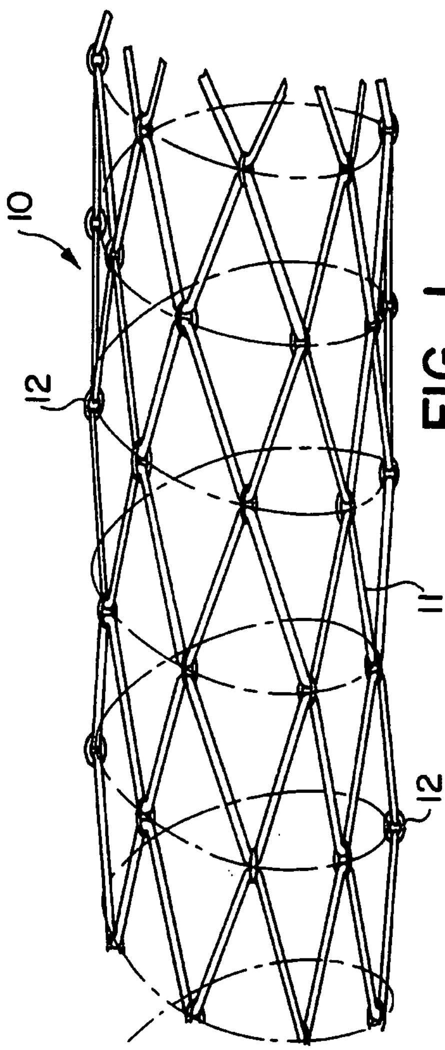

FIG. 1

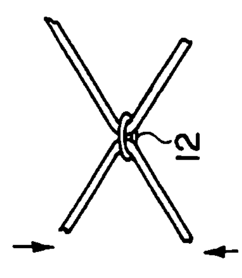

FIG. 2

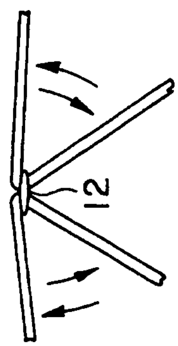

FIG. 3

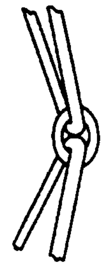

FIG. 4

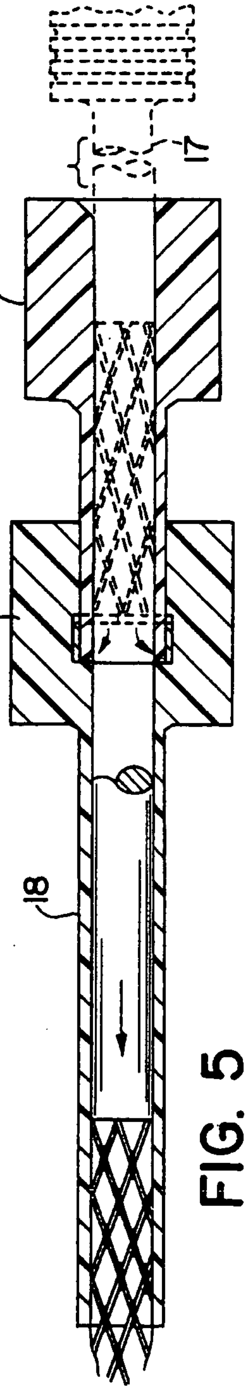

FIG. 5

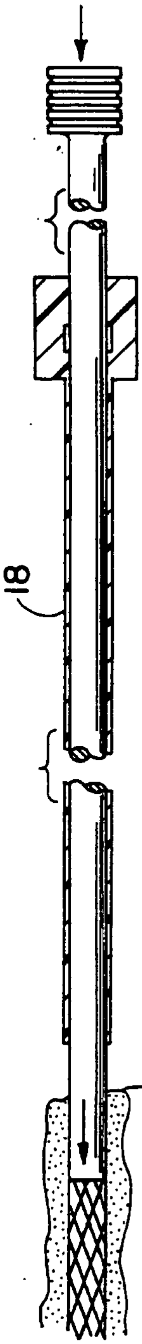

FIG. 6

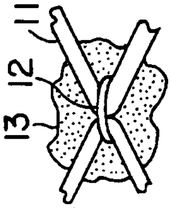

FIG. 9

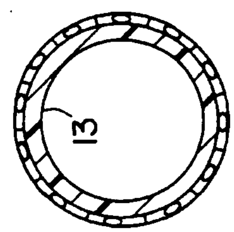

FIG. 8

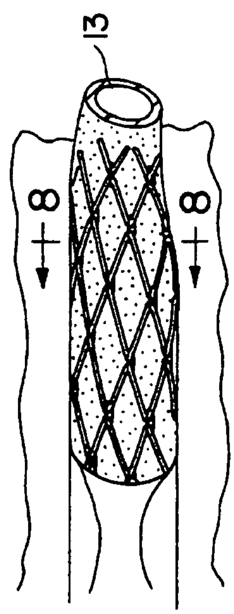

FIG. 7

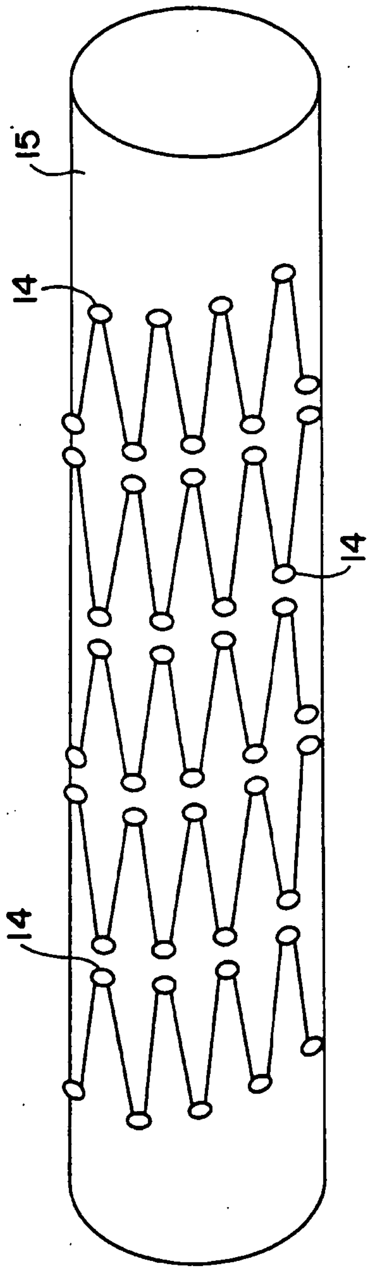

FIG. 10